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APPLICATION NUMBER / DATE of APPROVAL	DEVICE TRADE NAME	COMPANY NAME CITY, STATE, & ZIP	DEVICE DESCRIPTION / INDICATIONS
P860057/S037 **2/8/07** **Real-Time**	Carpentier-Edwards® PERIMOUNT® Pericardial Aortic Bioprosthesis Models 3000 and 3000TFX (aortic), and 6900P and 6900PTFX (mitral)	Edwards Lifesciences LLC Irvine , CA 92614	Approval for a reduction in the stitch density of the anchor stitch seamline and final alternating stitch seamline process of the bioprosthetic stent subassembly.
P860057/S041 **2/13/07** **Real-Time**	Carpentier-Edwards® PERIMOUNT® Pericardial Aortic Bioprosthesis Models 3000 and 3000TFX	Edwards Lifesciences LLC Irvine , CA 92614	Approval for a manufacturing process enhancement for the Carpentier-Edwards® PERIMOUNT® Pericardial Aortic Bioprosthesis Models 3000 and 3000TFX polyester band/Elgiloy band sub-assembly joining technique consisting of sewing through all of the band holes.
P910077/S066 **2/8/07** **Real-Time**	All Pulse Generator Models	Guidant Corp. St. Paul . MN 55112	Approval for the Guidant Pulse Generator replacement Guide which provides implanting physicians with general advice about removal and replacement of pulse generators reaching end of life.
P940031/S059 **2/8/07** **Real-Time**	All Pulse Generator Models	Guidant Corp. St. Paul . MN 55112	Approval for the Guidant Pulse Generator replacement Guide which provides implanting physicians with general advice about removal and replacement of pulse generators reaching end of life.
P950022/S033 **2/15/07** **135-Day**	Riata ST Family of Leads	St. Jude Medical, CRMD Sylmar , CA 91342	Approval to add an automated trimming fixture to trim excess silicone adhesive on the shock electrodes during production of the Riata ST family of leads.
P950037/S050 **2/13/07** **Real-Time**	Philos DR-T and Cylos DR-T	Biotronik, Inc. Lake Oswego , OR 97035	Approval for modifications to the CardioMessenger and CardioMessenger II used with the referenced devices. The devices, as modified, will be marketed under the trade names: CardioMessenger TLine and CardioMessenger II LLT and are indicated for transmitting diagnostic patient data from the device to the physician.
P960004/S038 **2/28/07** **135-Day**	FINELINE II & THINLINE II Atrial Leads	Boston Scientific Corporation St. Paul , MN 55112	Process change to the FINELINE II and THINLINE II J-forming manufacturing method to improve retention characteristics of the atrial J-shape.
P960040/S135 **2/8/07** **Real-Time**	All Pulse Generator Models	Guidant Corp. St. Paul . MN 55112	Approval for the Guidant Pulse Generator replacement Guide which provides implanting physicians with general advice about removal and replacement of pulse generators reaching end of life.
D970003/S081	All Pulse Generator	Guidant Corp.	Approval for the Guidant Pulse Generator replacement Guide

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2/8/07 Real-Time	Models	St. Paul . MN 55112	which provides implanting physicians with general advice about removal and replacement of pulse generators reaching end of life.
P980016/S090 2/15/07 Real-Time	Virtuoso Models D154AWG/ D154VWC Implantable Device	Medtronic, Inc. Shoreview , MN 55126	Approval for firmware updates to 1) address a “soft” rate limit Power on reset, 2) load a temperature sensitivity update at the time of manufacturing, and 3) load OptiVol enhancements (for use outside of the United States only) at the time of manufacturing.
P980037/S019 2/2/07 135-Day	XMI™ and XMI™-RX Thrombectomy Catheters	Possis Medical, Inc. Minneapolis , MN 55433	Approval for a change in sequence for the coating application of the catheter assembly.
P010012/S142 2/8/07 Real-Time	All Pulse Generator Models	Guidant Corp. St. Paul . MN 55112	Approval for the Guidant Pulse Generator replacement Guide which provides implanting physicians with general advice about removal and replacement of pulse generators reaching end of life.
P020009/S033 2/12/07 135-Day	Express 2 Coronary Stent System	Boston Scientific Cardiovascular Maple Grove , MN 55311	Approval to add an automated stent inspection step for the stent component of the device.
P020047/S007 2/9/07 Real-Time	MULTI-LINK VISION® Coronary Stent System and MULTI-LINK MINI Vision® Coronary Stent System	Abbott Vascular Temecula , CA 92591	Approval for minor modifications to the W-crest portion of both MULTI-LINK VISION® Stent Systems as well as a non-linear link shift to the Medium design MULTI-LINK VISION® Coronary Stent System.
P030005/S039 2/8/07 Real-Time	All Pulse Generator Models	Guidant Corp. St. Paul . MN 55112	Approval for the Guidant Pulse Generator replacement Guide which provides implanting physicians with general advice about removal and replacement of pulse generators reaching end of life.
P030025/S039 2/12/07 135-Day	TAXUS Express 2 Paclitaxel-Eluting Coronary Stent System	Boston Scientific Cardiovascular Maple Grove , MN 55311	Approval to add an automated stent inspection step for the stent component of the device.
P030054/S034 2/2/07 180-Day	St. Jude Medical Epic™ + HF Model V-352, Atlas Ò + HF Model V-344, Epic II + HF Model V-356 and Atlas II + HF Model V-	St. Jude Medical Cardiac Rhythm Management Division Sunnyvale , CA 94086	Approval for the addition of the AF Suppression Pacing feature. The systems listed above are indicated as follows: The system is intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. AF suppression pacing is indicated for suppression of paroxysmal or persistent atrial

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	366 Cardiac Resynchronization Therapy Defibrillators		fibrillation in patients with the above ICD indication and sinus node dysfunction. In patients indicated for an ICD, the system is also intended: 1) to provide a reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy (as defined in the clinical trials section) and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration; 2) to maintain synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic (permanent) atrial fibrillation and have NYHA Class II or III heart failure.
P040003/S002 **2/27/07** **180-Day**	ExAblate® 2000 System	InSightec- North America Dallas , TX 75207	Approval to implement the version 4.2 software and a new patient table (with other related hardware) that allow for operation of the ExAblate® 2000 System with the General Electric 3T Magnetic Resonance Imaging (MRI) System. Version 4.2 software provides for an interleaved mode of operation, elongated focal spots, and a scale-able cooling during.
P040016/S018 **2/12/07** **135-Day**	Liberté MR & OTW Coronary Stent System	Boston Scientific Cardiovascular Maple Grove , MN 55311	Approval to add an automated stent inspection step for the stent component of the device.
P040037/S002 **2/8/07** **180-Day**	GORE VIABAHN® Endoprosthesis	W.L. Gore & Associates, Inc. Flagstaff , AZ 86003	Approval for modifications to the endoprosthesis and delivery catheter design to reduce the overall delivery profile of the device by one french size.
P040038/S007 **2/5/07** **180-Day**	XACT Carotid Stent	Abbott Vascular Devices Santa Clara , CA 95054	Approval of the post-approval study.
P050007/S001 **2/2/07** **Panel**	StarClose™ Vascular Closure System, Model 1004, Version 2.10	Abbott Vascular Devices Redwood City , CA 94063	Approval for the StarClose™ Vascular Closure System. This device is indicated as follows: The StarClose™ Vascular Closure System is indicated for the percutaneous closure of common femoral artery access sites while reducing times to hemostasis and ambulation, in patients who have undergone diagnostic or interventional endovascular catheterization procedures utilizing a 5F or 6F procedural sheath. The StarClose™ Vascular Closure System is indicated for the

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			percutaneous closure of common femoral artery access sites while reducing time to dischargeability in patients who have undergone diagnostic endovascular catheterization procedures utilizing a 5F or 6F procedural sheath.
P050023/S003 2/13/07 Real-Time	Kronos LV-T CRT-D and Lumax Family of ICDs	Biotronik, Inc. Lake Oswego , OR 97035	Approval for modifications to the CardioMessenger and CardioMessenger II used with the referenced devices. The devices, as modified, will be marketed under the trade names: CardioMessenger TLine and CardioMessenger II LLT and are indicated for transmitting diagnostic patient data from the device to the physician.
P950020/S024 2/2/07	Cutting Balloon™ Ultra 2 Monorail (MR) PTCA Catheter (Cutting Balloon)	Boston Scientific Corporation San Diego , CA 92123	Change in the sterilization method as well as a change in dimensions of the outer shipping box for the Cutting Balloon™.
P950020/S025 2/23/07	Cutting Balloon™ Ultra 2 Monorail	Boston Scientific Corporation San Diego , CA 92123	Addition of in-process and post-sterile destructive pull tests.
P960040/S140 2/15/07	Vitality and Vitality AVT Family of Cardiac Resynchronization Therapy Defibrillators (CRT-D)	Guidant Corp. St. Paul , MN 55112	Modifications to several device functional tests.
P960040/S142 2/16/07	VITALITY HE Cardiac Resynchronization Therapy Defibrillator (CRT-D)	Guidant Corp. St. Paul , MN 55112	Changes to the solder ball inspection testing process.
D970003/S083 2/21/07	PULSAR / PULSAR MAX / INSIGNIA / NEXUS Pulse Generators	Guidant Corp. St. Paul , MN 55112	Addition of an inspection step and adjusted equipment settings.
D970003/S084 2/28/07	INSIGNIA / MNEXUS Family of Devices	Guidant Corp. St. Paul , MN 55112	Changes to the curing process of the underfill epoxy on hybrid components of INSIGNIA/NEXUS family of devices for throughput and yield improvement.
P970020/S048	Multi-Link Vision®	Abbott Vascular, Inc.	Modification in the dose range and conveyor speed for e-beam

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2/16/07	Coronary Stent System	Temecula , CA 92591	sterilization for the Multi-Link® and Multi-Link Vision® Coronary Stent Systems.
P990020/S025 2/23/07	Medtronic Vascular AneuRx Stent Graft with Xcelerant Delivery System	Medtronic Vascular Santa Rosa , CA 95403	Change to the manufacturing process to include an alternative location for a catheter coating operation.
P010012/S147 2/16/07	CONTAK RENEWAL 3 Pulse Generator	Guidant Corp. St. Paul , MN 55112	Changes to the solder ball inspection testing process.
P010015/S026 2/23/07	Attain® Over The Wire Left Ventricular Model 4193 Lead	Medtronic, Inc. Shoreview , MN 55126	Minor changes to the connector assembly.
P020040/S002 2/2/07	NIRFLEX™ Pre-Mounted Coronary Stent System	Medinol, LTD. Tel-Aviv , Israel 61581	Change to the ETO load configuration for sterilization of the device.
P020040/S003 2/2/07	NIRFLEX™ Pre-Mounted Coronary Stent System	Medinol, LTD. Tel-Aviv , Israel 61581	Change in the welding process in the manufacture of the device.
P020040/S004 2/15/07	NIRFLEX™ Premounted Coronary Stent System	Medinol Ltd. Boston , MA 02109	Change to the PCD configuration used during the EtO sterilization process and removal timing for the incubation of the BIs used during the EtO sterilization process.
P020040/S005 2/15/07	NIRFLEX™ Premounted Coronary Stent System	Medinol Ltd. Boston , MA 02109	Use of an automated stent-Weighing machine during the manufacture of the NIRFLEX™ Stent.
P020047/S008 2/16/07	Multi-Link® Coronary Stent System	Abbott Vascular, Inc. Temecula , CA 92591	Modification in the dose range and conveyor speed for e-beam sterilization for the Multi-Link® and Multi-Link Vision® Coronary Stent Systems.
P030005/S041 2/16/07	CONTAK RENEWAL TR Cardiac Resynchronization Therapy Pacemaker (CRT-P)	Guidant Corp. St. Paul , MN 55112	Changes to the solder ball inspection testing process.